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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,864	06/07/2005	Jeanine D Mattson	AH01646K	8020
24265 7590 05/22/2008 SCHERING-PLOUGH CORPORATION PATENT DEPARTMENT (K-6-1, 1990) 2000 GALLOPING HILL ROAD KENILWORTH, NJ 07033-0530				
EXAMINER				
DEBERRY, REGINA M				
ART UNIT		PAPER NUMBER		
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05/22/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/537,864

Applicant(s)

MATTSON ET AL.

Examiner

Regina M. DeBerry

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 February 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 and 48-51 is/are pending in the application.
4a) Of the above claim(s) 6-31 and 43-45 is/are withdrawn from consideration.
5) ☒ Claim(s) 1-3, 5 and 48-51 is/are allowed.
6) ☒ Claim(s) 4 and 32-42 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/08.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

Status of Application, Amendments and/or Claims

The amendment and Applicant's arguments (filed 13 February 2008) have been entered in full. Claims 6-31, 43-45 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. Claims 46 and 47 were canceled. New claims 48-51 were entered. Claims 1-5, 32-42 and 48-51 are under examination.

Information Disclosure Statement

The information disclosure statement(s) (IDS) filed 13 February 2008 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Withdrawn Objections And/Or Rejections

The specification is in compliance with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations.

The rejection to claims 4, 32-42 under 35 U.S.C. 112, second paragraph, as set forth at pages 3-4 of the previous Office Action (07 November 2007), is *withdrawn* in view of the amendment (13 February 2008).

The rejection to claim 4 under 35 U.S.C. 112, first paragraph, written description, as set forth at pages 4-6 of the previous Office Action (07 November 2007), is *withdrawn* in view of the amendment (13 February 2008).

The rejection to claim 3 under 35 U.S.C. 102(e) as being anticipated by Boyle et al., U.S. Patent No. 6,316,408 B1, as set forth at page 7 of the previous Office Action (07 November 2007), is *withdrawn* in view of the amendment (13 February 2008).

NEW CLAIM REJECTION/OBJECTIONS

Claim Objections

Claim 4 is objected to because of the recitation, "hybridizes under a stringent conditionss". The instant recitation does not grammatically agree with the plural recitation of "...wherein said stringent conditionss...". Amending the claim to recite, "hybridizes under stringent conditions" would be remedial.

Claim Rejections-35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 37 and 38 recite the limitation "immunogenic composition". There is insufficient antecedent basis for this limitation in the claims.

Claim Rejections-35 USC § 112, First Paragraph, Written Description, New Matter

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

Applicant's amendment, filed 13 February 2008, asserts that no new matter has been added and directs support to page 30, lines 9-10 for the written description for the above-mentioned hybridization conditions.

The specification as originally filed does not provide support for the invention as now claimed because instant claim 4 is missing the wash conditions as recited on page 30, lines 10-12. The instant claim recites incomplete hybridization conditions and now recites limitations which were not disclosed in the specification as filed. Claim 4 changes the scope of the instant disclosure as-filed and results in new matter.

Applicant is required to cancel the new matter in the response to this Office action. Amending claim 4 to recite the wash conditions as recited on page, 30, lines 10-12 would obviate the instant rejection.

Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Rejections-35 USC § 102(e)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 32-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Anderson et al., US Patent No. 6,838,262 B1.

The instant claims are drawn to an isolated nucleic acid molecule comprising an open reading frame encoding a canine receptor activator of the NF-kB ligand comprising the amino acid sequence of SEQ ID NO:2 or a fragment thereof, wherein said fragment binds to a canine receptor activator of NF-kB.

Anderson et al. teach a nucleic acid sequence which has 91% percent identity to a nucleic acid encoding SEQ ID NO:2. Please see sequence query (Appendix A; Result #11; SEQ ID NO:12) and Anderson et al. (SEQ ID NO:12; columns 61-64). Anderson et al. teach recombinant methods of making the recombinant protein, plasmid vectors, promoters, secretory leader peptides, prokaryotic, yeast, insect and eukaryotic host cells (column 10, line 65-column 13, line 3).

Based on the 91% sequence identity between the nucleic acid of Anderson et al. (SEQ ID NO:12) and a nucleic acid encoding SEQ ID NO:2, the limitations of instant claim 32 (i.e. nucleic acid encoding a fragment of SEQ ID NO:2), and absence of

evidence to the contrary, the sequence of Anderson et al. would have the activity of binding a canine receptor activator of NF- κ B and thus anticipates the claims.

Conclusion

Claims 4 and 32-42 are rejected.

Claims 1-3, 5 and 48-51 are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

RMD
5/15/08